

Attorney Docket No. 9233.54

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Serial No.: 09/873,899

Filed: June 4, 2001

For: *Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making Same*

Confirmation No.: 5139

Group Art Unit: 1654

Examiner: Russel, Jeffrey E.

Date: April 23, 2003

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Commissioner for Patents  
Washington, DC 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Attached is a list of documents on form PTO-1449 together with a copy of each identified document. This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(c), before final Office Action or Allowance.

A check in the amount of \$180.00 is enclosed as payment of the fee in accordance with 37 C.F.R. § 1.17(p). This amount is believed to be correct; however, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

*Mary L. Miller*

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Registration No. 39,303

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*Monica L. Croom*  
Monica L. Croom

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

Of

2

Application Number

09/873,899

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First Named Inventor

Ekwuribe

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Examiner Name

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## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (Class/Subclass)
		Number	Kind Code (if known)			
JR	1	4,223,163		Guilloty	09/16/1980	568/618
JR	2	4,801,575		Pardridge	01/31/1989	514/4
JR	3	5,099,074		Mueller et al.	03/24/1992	568/617
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## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (Class/Subclass)	T
		Office	Number	Kind Code (if known)				
JR	16	DE	196 32 440 A1		BASF AG	02/19/1998		
JR	17	EP	0 822 218 A2		Glenn A. Miller, Michael W. Jorgenson, Richard Budnik	02/04/1998		
JR	18	JP	01207320 (Abstract Only)		Daicel Chem Ind Ltd.	08/21/1989		
JR	19	PCT	WO 97/14740		Receptagen Corporation, University of Washington	04/24/1997		
JR	20	PCT	WO 01/12230		Myung-Ok Park, Kang Choon Lee	02/22/2001		

## OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
JR	21	Francis, G.E., et al., <i>Polyethylene Glycol Modification: Relevance of Improved Methodology to Tumour Targeting</i> , <i>Journal of Drug Targeting</i> , Vol. 3, pp. 321-40 (1996)	
JR	22	Guzman, Angel, et al., <i>Effects of Fatty Ethers and Stearic Acid of the Gastrointestinal Absorption of Insulin</i> , <i>PRHSJ</i> , Vol. 9, No. 2, pp. 155-159 (August 1990)	

Examiner Signature

Jeffrey E. Russel

Date Considered

June 2, 2003

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## OTHER NON PATENT LITERATURE DOCUMENTS

JR	23	Krishnan, B. Radha, et al., <i>Stability and Physical Characteristics of Orally Active Amphiphilic Human Insulin Analog, Methoxy (Polyethylene Glycol) Hexanoyl Human Recombinant Insulin (HIM2)</i> , <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , Vol. 27 pp. 1038-39 (2000)	
JR	24	Lindsay, D.G., et al., <i>The Acetylation of Insulin</i> , <i>Biochem J.</i> , Vol. 121, pp. 737-745 (1971)	
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JR	26	Moghaddam, Amir, <i>Use of polyethylene glycol polymers for bioconjugations and drug development</i> , <i>American Biotechnology Laboratory</i> , pp. 42, 44 (July 2001)	
JR	27	Neubauer, H. Paul, et al., <i>Influence of Polyethylene Glycol Insulin on Lipid Tissues of Experimental Animals</i> , <i>Diabetes</i> , Vol. 32, pp. 953-58 (October 1983)	
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JR	29	Sirokman, Geza, et al., <i>Refolding and proton pumping activity of a polyethylene glycol-bacteriorhodopsin water-soluble conjugate</i> , <i>Protein Science</i> , Vol. 2, pp. 1161-1170 (1993)	
JR	30	Torchilin, Vladimir P., <i>Immunoliposomes and PEGylated Immunoliposomes: Possible Use for Targeted Delivery of Imaging Agents</i> , <i>Immunomethods</i> , Vol. 4, pp. 244-58 (1994)	
JR	31	Wei, Jiang, et al., <i>A Poly(Ethylene Glycol) Water-soluble Conjugate of Porin: Refolding to the Native State</i> , <i>Biochemistry</i> , Vol. 34, pp. 6408-6415 (1995)	
JR	32	Xia, Jiding, et al., <i>Effects of polyoxyethylene chain length distribution on the interfacial properties of polyethylene glycol n-dodecyl ether</i> , <i>Yingyong Huaxue</i> , Vol. 2, No. 4, pp. 59-65 (Abstract Only) (1985)	
JR	33	Zalipsky, Samuel, et al., <i>Peptide Attachment to Extremities of Liposomal Surface Grafted PEG Chains: Preparation of the Long-Circulating Form of Laminin Pentapeptide, YIGSR</i> , <i>Bioconjugate Chem.</i> , Vol. 6, pp. 705-8 (1995)	

Examiner Signature

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June 2, 2003

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